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Re:	10/809,140	**CC:**	

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•Comments:

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of Chaouk et al.

Filing Date: March 25, 2004

Examiner: Daniels, M.

Serial No.: 10/809,140

Art Unit: 1732

Title: Hydrogel String Medical Device

Mail Stop Appeal Brief- Patents
Commissioner for Patents
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APPEAL BRIEF

The following comments are submitted in Appeal of the above referenced patent application. This Appeal Brief is accompanied by the fee set forth in 37 CFR §1.17(c) ($500.00). A Notice of Panel Decision from Pre-Appeal Brief Review was mailed on December 21, 2005. The Notice of Appeal was filed on December 9, 2005.

(1) Real party in interest

The real party in interest in this Appeal is the Assignee, BioCure, Inc.

(2) Related appeals and interferences

There are no related appeals or interferences.

(3) Status of claims

Claims 1-8 are pending and on appeal.

(4) Status of amendments

No claim amendments were filed subsequent to final rejection.

(5) Summary of claimed subject matter

The claimed invention is a method for forming a hydrogel string. The method uses a delivery device 10 (page 6, line 13 – page 8, line 17) having a gelation chamber 36 (page 6, lines 22-24, page 7, lines 20-22, and Figure 2). A prepolymer and a gelation initiator are combined to form the hydrogel in this gelation chamber (page 3, lines 8-9 and 21-26). After formation of the hydrogel in the gelation chamber 36, the hydrogel is extruded from the delivery device as a hydrogel string (page 3, lines 7-8, page 9, lines 21-23)

Claims 2-5 and 8 specify that the delivery device is a catheter (claim 2- page 6, line 18); a multilumen catheter (claim 3- page 3, lines 20-21); a multilumen catheter having a gelation chamber (claim 4- page 3, lines 22-23); or a coaxial dual lumen catheter where the inner catheter is slidable within the outer catheter and controls the gelation of the hydrogel string (claim 8, page 3, lines 24-25).

Claim 6 specifies that the prepolymer composition is at least two solutions that form a hydrogel when combined (page 3, lines 17-26).

Claim 7 specifies that the hydrogel is extruded from one end of the gelation chamber as the prepolymer is moved into the other end of the gelation chamber (page 9, lines 18-24).

(6) Ground of rejection to be reviewed on appeal

(i) Whether 1-8 are obvious under §103(a) over U.S. Patent No. 6,152,943 to Sawhney ("Sawhney") in view of U.S. Patent No. 5,443,454 to Tanabe ("Tanabe").

The claims stand or fall together.

(7) Argument

Claims 1-8 are not obvious over Sawhney in view of Tanabe

Sawhney teaches a method and device for forming a hydrogel in situ- in a body cavity or void. Figure 3 illustrates one embodiment of the device, where 46 represents a mixing chamber. In the method, prepolymer solutions are injected through the lumens 49 and 49' into the chamber 46. The prepolymer solutions begin mixing in the chamber and the partially formed gel is extruded through the outlet ports 47 into the lumen or void. (See column 9, line 55 though column 10, line 24).

Sawhney teaches away from the invention

Sawhney teaches away from premature formation of the hydrogel, meaning formation of the hydrogel before it is at the body cavity or void. This point of the invention is stated very clearly several times, such as in the abstract "deliver two or more fluent prepolymer solutions **without premature crosslinking**" and col. 1, lines 8-10 "delivering two or more liquid components to form a hydrogel implant **in situ**" (emphasis added).

The paragraph beginning at col. 3, line 7 reads:

> In accordance with the present invention, delivery systems are provided for delivering separate prepolymer components of a hydrogel system, without premature crosslinking within the delivery system. In one embodiment, the delivery system includes an occlusive element for anchoring a distal end and isolating the region in which the hydrogel is to be formed in situ. In another embodiment, the delivery system may include variable stiffness regions to enable passage through tortuous anatomy. In yet another embodiment, the delivery system includes a steerable tip. In still further alternative embodiments, the prepolymer components of the hydrogel system may be mixed together in a mixing chamber disposed in a distal region of the delivery system, and then extruded into the body lumen or void during the crosslinking process, to reduce washout or dilution of the components (emphasis added).

The embodiment illustrated by Figure 3 (which has been discussed in the prosecution history of this application by Applicants as well as the Examiner) is one embodiment of the delivery systems- all of which are used to deliver a hydrogel system without premature crosslinking.

The embodiment of Figure 3 is discussed further at col. 10, lines 1-25:

> Delivery system 40 therefore prevents premature crosslinking of the prepolymer solutions, while also enabling the solutions to be mixed and partially gelled before being deposited in the body lumen or void. Delivery system may be especially useful in depositing hydrogel systems that form both physical and chemical crosslinks, wherein the physical crosslinking is accomplished by mixing the prepolymer solutions in mixing chamber 46. The partial gel extruded from mixing chamber 46 through outlet ports 47 then may have sufficient mechanical integrity to remain in position in the body lumen or void during the chemical crosslinking process (emphasis added).

The Examiner argues that the "partially formed" gel taught by Sawhney that is extruded from the mixing chamber would "obviously or inherently existed with some string-like

PAGE 6/11 * RCVD AT 2/9/2006 3:29:48 PM [Eastern Standard Time] * SVR:USPTO-EFXRF-6/25 * DNIS:2738300 * CSID:4043774015 * DURATION (mm-ss):05-20

characteristics." This is an unsupported statement. In fact the opposite is true- all statements in Sawhney teach away from this statement by the Examiner. Perhaps the primary definition for "extrude" found in the online edition of Merriam-Webster's dictionary http://www.m-w.com/dictionary/extrude should be used: "1 : to force, press, or push out". A glob of partially formed gel can be "extruded" from a catheter, and this is more likely what is taught by Sawhney. A glob of partially formed gel pushed from a catheter could have a number of "shapes" or no shape at all. The Examiner's statement that it would "obviously" have "string-like characteristics" is baseless.

The combination of Sawhney and Tanabe

In the Office Action of May 20, 2005 the Examiner states that "Sawhney appears to be silent to forming or extruding a string" (page 4). The Examiner however states that this aspect of the invention is taught by Tanabe and that it would be obvious to combine Sawhney and Tanabe in order to avoid leakage of the embolic material out of the site.

The Applicants have pointed out how Sawhney teaches away from the claimed invention. Sawhney teaches away from forming the hydrogel within the catheter and extruding it from the catheter as a string. Sawhney explicitly teaches avoiding premature crosslinking of the hydrogel.

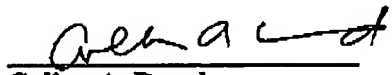
Sawhney recognized this issue of dispersion of the embolic material and provided a solution to the problem - delivering a partially polymerized product. One of skill in the art in reading Sawhney would not be motivated to provide a solid composition as taught by Tanabe since Sawhney already teaches a solution. Furthermore, Sawhney specifically teaches to **not** deliver a solid hydrogel.

The Examiner has improperly engaged in hindsight to modify Sawhney to reproduce the invention that is claimed. In re Fritch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992); Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985); W.L. Gore & Assoc. v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-313 (Fed. Cir. 1983) ("To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein only that which the inventor taught is used against its teacher").

CONCLUSION

The cited references do not teach or suggest the claimed invention. Accordingly, it is respectfully submitted that the claims should be allowed over the art and rejections of record.

Respectfully submitted,



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Collen A. Beard

Date: February 9, 2006

Appendix- Listing of Claims Involved in the Appeal

1. A method for forming a hydrogel string comprising the steps:

providing a delivery device having a gelation chamber;

providing a prepolymer composition that will form a hydrogel when brought into contact with a gelation initiator;

contacting the prepolymer with the gelation initiator in the gelation chamber so that it forms a hydrogel in the gelation chamber; and

extruding the hydrogel from the delivery device as a hydrogel string.

2. The method of claim 1, wherein the delivery device is a catheter.

3. The method of claim 2, wherein the delivery device is a multilumen catheter.

4. The method of claim 1, wherein the delivery device is a catheter having at least two lumens and a gelation chamber at the distal end.

5. The method of claim 4, wherein the catheter is a coaxial catheter having an inner catheter and an outer catheter and the method further comprises the step of step of sliding the inner catheter within the outer catheter to increase or decrease the length of the gelation chamber.

6. The method of claim 1, wherein the prepolymer composition comprises at least two solutions that will form a hydrogel when combined in the gelation chamber.

7. The method of claim 1, wherein the hydrogel is extruded as prepolymer composition is moved into the gelation chamber.

8. The method of claim 1, wherein the delivery device is a coaxial dual lumen catheter and the inner catheter is slidable within the outer catheter so that the degree of formation of the

hydrogel string as it exits the gelation chamber can be altered as the inner catheter is slid towards the distal end of the gelation chamber.

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